Application No.: 10/092,955 Docket No.: 022719-0022

REMARKS

The undersigned attorney for Applicant thanks Examiner Maiorino for extending the courtesy of a personal interview on January 27, 2005. Although no agreement was reached, substantial progress was made in explaining to the Examiner how the pending claims distinguish over the cited art.

Claims 1 and 14 have been amended, as discussed during the interview, to make it clear that the control unit is effective to compile and store a database of sensed data. This amendment is believed to clarify that "compiling" a database of such information inherently involves storing the information. Support for this amendment is found throughout the specification, including at page 12, lines 13-21.

Ų.

4

The Examiner rejects claims 1-15 and 17-20 pursuant to 35 USC §102(e) as being anticipated by each of Rise (US 6,263,237), Natarajan (US 6,501,983), and Ishiwaka (US 6,464,687). Applicant respectfully traverses this rejection for the reasons explained during the interview and as discussed below.

Rise is primarily directed to stimulation plus drug delivery treatment protocols. Although it makes some mention of a closed loop system, it is not specific about the capabilities of such a system. In particular, Rise does not disclose, as required by claim 1, a drug delivering system having a control unit that is effective to compile and store a database of sensor output signals and to communicate a delivery signal that is continuously adjusted based on the database of sensor output signals. Similar limitations also appear in claims 14 and 20, which likewise are not disclosed by Rise. For these reasons, Applicant submits that the pending claims distinguish over the Rise reference.

Natarajan similarly fails to disclose the claimed invention. Natarajan, which is primarily directed towards cardiac event monitoring and treatment, makes only passing reference to drug delivery. The drug delivery disclosed by Natarajan is limited to sensing a parameter and issuing a drug release signal. Like Rise, this reference fails to disclose a drug delivering system having a control unit that is effective to compile and store a database of sensor output signals and to communicate a delivery signal that is continuously adjusted based on the database of sensor output signals. Natarajan thus fails to anticipate the pending claims.

Application No.: 10/092,955 Docket No.: 022719-0022

Ishikawa is perhaps even less relevant than the two preceding references. Ishikawa is directed to a miniature drug delivery capsule system that uses one or more semiconductor balls to help control drug delivery. Like Rise, it makes little mention of a closed loop system, and it contains few specifics of a closed-loop drug delivery system. As explained during the interview, this reference fails to anticipate the pending claims because it does not disclose a drug delivering system having a control unit that is effective to compile and store a database of sensor output signals and to communicate a delivery signal that is continuously adjusted based on the database of sensor output signals. Accordingly, the rejection based on Ishikawa must be withdrawn.

In view of the amendments and remarks above, Applicants submit that claims 1-15 and 17-20 are in condition for allowance. Applicants encourage the Examiner to telephone the undersigned upon receipt of this response to discuss any issues that may remain.

Dated: February 14, 2005

Ç

Respectfully submitted,

William C. Geary III

Registration No.: 31,359

NUTTER MCCLENNEN & FISH LLP

World Trade Center West 155 Seaport Boulevard

Boston, Massachusetts 02210-2604

(617) 439-2000

(617) 310-9000 (Fax)

Attorney for Applicant

1398058.1